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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,722	09/08/2000	Pramod K. Srivastava	8449-115-999	8697

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[REDACTED] EXAMINER

YAEN, CHRISTOPHER H

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1642

DATE MAILED: 10/22/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/657,722	SRIVASTAVA, PRAMOD K.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 August 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19-51 is/are pending in the application.
- 4a) Of the above claim(s) 20,21 and 32-51 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 19 and 22-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

1. The amendment filed 8/5/02 (paper no.8) is acknowledged and entered into the record. Claims 19-51 are pending in the instant application, claims 20-21, 32-51 are withdrawn from consideration as being drawn to non-elected subject matter. Therefore, claims 19, 22-31 are examined on the merits.

### ***Claim Rejections Withdrawn***

2. The rejection of claims 19, 22-23, and 25-31 under 35 USC § 112, 2<sup>nd</sup> paragraph, as being indefinite is withdrawn in view of the amendments and arguments set forth by the applicant.

3. The rejection of claims 19, and 22-31 under 35 USC § 112, 1<sup>st</sup> paragraph as being enabled for hsp 70, 90 and gp96 but not enabled for all stress proteins is removed in light of the arguments set forth by the applicant.

### ***Claim Rejections Maintained***

4. The rejection of claim 24 under 35 USC § 112, 2<sup>nd</sup> paragraph as being indefinite in the recitation of the phrase “low pH”, is maintained. The arguments set forth by the applicant have been carefully considered but are not found persuasive for the following reason. Applicant argues that one of skill in the art would understand that “low pH” is intended to mean an acidic solution. Although it is understood that pH that is less than 7 is considered an acidic solution, the term “low” as used in claim 24, is a relative term. Depending on the initial pH of a solution, any pH below the initial level is considered low and may not necessarily refer to an acidic solution (i.e. a solution of initial pH=10 with a final pH=8).

***New Claim Rejections***

***Claim Rejections - 35 USC § 112***

5. Claims 19 and 22-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has not set forth peptides recovered or isolated from the separation of stress protein-peptide complexes derived from tumors, and therefore the written description is not commensurate in scope with the claims which read on peptides in general isolated from tumors.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The claims of the instant inventions are drawn to peptide compositions derived from the separation of a stress protein and its associated peptide. Although the stress-protein-peptide complex can be determined and isolated, the claims as currently recited read on any protein fragment or polypeptide fragment that is derived from a tumor cell

from which the complex was initially extracted. One of skill in the art would not be able to determine with any certainty what the composition comprises because the polypeptide and or peptides themselves have not been adequately described. There is a lack of characterization of the peptide or peptides, which makes up the composition, wherein detailed information regarding the structure or amino acid sequence of the peptide or peptides has not been provided in the specification. Furthermore, because the specification has not described the structure and makeup of the peptides in the composition, it can be equivalent to any known composition wherein the composition comprises a peptide or protein fragment.

6. Claims 19 and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 19 and dependent claims thereof, the recitation of the term "peptides" renders the claim indefinite because one of skill in the art cannot envision what the peptide is, the structure or the amino acid sequence and therefore the metes and bounds of the term cannot be determined.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Asano T (J. Immunother 1993 Nov;14(4):286-92). Claim 19 is drawn to a pharmaceutical

composition comprising peptides with a non-toxic carrier. Asano T *et al* teach of liposome-encapsulated tri-peptides used as an immunomodulator of monocytes and macrophages.

***Conclusion***

9. No claim is allowed. Because of the newly cited rejections made in the instant office action, this action is made **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
October 21, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600